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Study protocol and statistical analysis plan

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Effects on Patient Satisfaction and Gait After Loss of Peroneus Longus Function

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Study plan

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This study is one out of four studies that will make up my doctoral thesis. The study has been conducted for a bit over two years and is now in its final year. The data collected needs to be analysed and time and money set aside for this.

Hypothesis: The gait is minimally impaired by the loss of the peroneus longus function

BACKGROUND

The peroneus longus muscle is a strong evertor and plantar flexor of the foot. It also plantar flexes the first ray and stabilizes the transverse arch (Perry 1992). It is most active during the stance phase of the human gait (Hunt et al. 2001). Transfer of the peroneus longus tendon to the peroneus brevis has been suggested as a component of the cavus foot reconstruction (Ortiz and Wagner 2014) and in the case of a damaged peroneus brevis tendon (Redfern and Mayerson 2004). One might hypothesise a severe effect on the gait resulting from the loss of this important stabilizer of the foot, but patients seem to recover well after this tendon transfer (Redfern and Mayerson 2004, Molloy and Tisdell 2003). The peroneus longus has been used as an augmentation for anterior cruciate ligament reconstruction, and in a 5-9 year follow up, all patients have returned to sport with no weakness of their ankle (Kerimoglu 2008). There are no prospective studies of the effect on gait of a peroneus longus to brevis transfer.

It has been shown that certain parameters in plantar loading vary significantly between the normal foot and the cavo-varus foot: peak pressure, pressure time integral, maximum force, force time integral and area (Hillstrom et al. 2013). In the same study there was no significant difference in the gait pattern between foot types in subjects with healthy feet. In a dynamic study, pressure time integrals have been shown to be higher in patients with foot pain than in patients without pain, and higher in patients with cavo-varus feet than in normal feet (Burns et al. 2005).

Some studies using dynamic pedobarography have shown a rather poor correlation between the distribution of pressure and patient satisfaction (Metaxiotis et al. 2000). There is also indication that the correction achieved radiographically is not well correlated with the distribution of pressure (Chan et al. 2007).

Aim

In this prospective study we examine foot function (force and pressure) and gait variables of patients who have undergone a peroneus longus to brevis transfer, or who have had their peroneus longus tendon removed due to injury. We also look at patient satisfaction with a patient reported outcome measure (PROM). The aim of this study is to determine the extent to which the loss of the peroneus longus tendon affects the gait and post-operative patient satisfaction.

METHODS

Patient selection

The patients will be selected mainly from two groups: those undergoing cavo-varus foot reconstruction (calcaneal shift, Broströms ligament reconstruction and a peroneus longus to brevis transfer) and those having surgery for severe peroneus brevis or longus injuries and instability (Broströms ligament reconstruction and peroneus longus to brevis transfer). These two groups have in common that the surgery includes a peroneus longus to brevis transfer. In the second group

the surgeon will decide to transfer the peroneus longus tendon on the basis of clinical examination and/or ultrasound and MRI, indicating a high probability of damage to the peroneus longus tendon. When the surgery is planned the patient will be offered to take part in the study. Patients with neuro-muscular disorders will be excluded.

Procedures and outcome measures

The patients will be examined before surgery and follow up examinations will be made at 6 months and one year after the surgery. Together with a clinical examination, a weight-bearing X-ray including the Saltzman projection (Saltzman and El-Khoury 1995) will be performed before surgery and at six months follow-up. The Foot and Ankle Outcome Score (FAOS) will be used pre- and postoperatively (Roos et al. 2001) in conjunction with the self-reported health questionnaire SF-36. A gait analysis of the foot will be performed before and after surgery, using the GAITRite system (measuring pressure, force, symmetry and step length), the RsScan mat (measuring pressure) and the MoLab system (measuring 3D information about the gait with sensors on abdomen, pelvis, thigh, lower leg and foot). The gait analysis will be compared to a standardized normal rectus foot. The radiographs in this study will be taken primarily to ensure that all patients have a similar skeletal reconstruction.

Power

Sample size:

There are no previous studies of the gait after peroneus longus transfer. We have therefore assumed that the foot before surgery has varus hindfoot and after surgery a more neutral hindfoot. In a recent study pressure and force of 54 normal feet and 24 varus feet has been measured (Hillstrom et al. 2013). In this study there is a significant difference between peak pressure and force in the hallux between the two types of feet. The normal rectus foot had a mean peak pressure of 26.39 N/cm² (17.31 SD) and the varus foot had mean pressure 29.05 N/cm² (13.68 SD) with a difference of 9.27 N/cm² ($p=0.01$). The rectus foot had a mean force in the hallux of 110.1 N (40.91 SD) and varus feet had 83.93 N (34.68 SD). The difference between the feet is 10.39 N ($p=0.006$).

Assuming a standard deviation of 15 for the maximum pressure (N/cm²) and using a paired t-test with alpha of 0.05, we need to include 30 patients to have 80% power to detect a paired difference of 8 N/cm².

At the orthopaedic department in Uppsala seven peroneus longus to brevis transfers were performed during 2013, and in the same year two patients were diagnosed with a primary peroneus longus rupture. The study is planned to start in 2016 and to take three years in order to give a statistically acceptable sample size.

Data processing

Statistical analysis

Paired differences before and after treatment will be analyzed using a T-test.

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